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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,715	04/19/2000	MAMORU OHASHI	2000-0486A	9675

7590

11/04/2002

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,715

Applicant(s)

OHASHI ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 61-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 61-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt for Request for Extension of Time and Continued Prosecution Application received on August 22, 2002 is acknowledged. Claims 1-20 and 61-82 are included in the prosecution of this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 and 63-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negoro et al (5,258,382) in view of Muller et al (5,858,410).

Negoro et al teach the instantly claimed aldose reductase inhibitor compound in a pharmaceutical composition for the treatment of diabetes (see abstract). The reference discloses the aldose reductase inhibitor in fine granules (1%) with a diluent (73%), a binder (3%), a lubricant (1%), and disintegrator (22%) (See example 29).

Negoro et al does not specify the particle size of the active or the dissolution rate.

Muller et al teach pharmaceutical compositions containing an active that is insoluble or sparingly soluble. Muller discloses that the dissolution rate increases as the particles surface area increases in accordance with the Noyes-Whitney law. As a results of increased dissolution rate increases bioavailability (col. 1, lines 44-50). Muller discloses a marked increase in saturation solubility and in turn dissolution with the reduction of particle diameter and increased surface area from microns to nanometers

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(col.5, lines 58-60 and col. 7, lines 7-10). The reference teaches a particle in the range of 10 to 1,0000 nm and 65% dissolution rate within ten minutes (col. 14, lines 49-55 and figures).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to reduce the particle size of the active to less than 20 microns since Muller et al disclose that increased surface area through reduction of particle size allows a faster rate of dissolution. One would be motivated to do so with the expectation of similar results since Muller teaches a sparingly soluble or insoluble drug and the instant active agent is also sparingly soluble.

Claims 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negoro et al (5,258,382) in view of Muller et al (5,858,410) in further view of Schneider et al (5,356,636).

As set forth above, Negoro et al teach the instant active and Muller et al teach the instant particle sizes to increase dissolution. Muller et al teach the use of stabilizers to cover the surface of the particles to prevent aggregation (col. 7).

The references do not teach the instant acids in the composition.

Schneider et al teach the instant acids as stabilizers (col. 4, lines 68) in compositions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instant acids since Schneider et al teach these acids as stabilizers for the actives.

Response to Arguments

Applicant's arguments have been fully considered and are considered persuasive in regards to the combination of Negoro et al and Bavitz et al. However, the examiner retains Negoro et al to teach the instant active in a pharmaceutical composition containing the recited excipients in instant amounts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

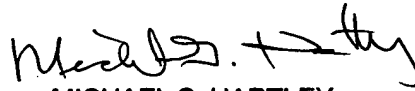
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG



October 24, 2002



MICHAEL G. HARTLEY
PRIMARY EXAMINER